

R E M A R K S

Careful consideration has been given to the Official Action of June 2, 2006, and reconsideration of the application as amended is respectfully requested.

Claim Status

Claims 46-53 are withdrawn from further consideration on the basis of a prior election.

Claims 1, 4-5, 6-7, 12, 13, 22-23, 26-28, and 38-41 have been rejected under 35 U.S.C. 102 as being anticipated by Medoff (U.S. 5,709,682).

Claims 2-3, 14-21, 30-34 and 35-37 have been rejected under 35 U.S.C. 103 as being unpatentable over Medoff '682 in view of Wellisz (U.S. 6,302,884).

Claims 24-25 are rejected under 35 U.S.C. 103 as being unpatentable over Medoff '682.

Claims 11 and 45 have been indicated as containing allowable subject matter.

Amendatory Action and Argument

Claims 46-53 drawn to the non-elected invention have been cancelled without prejudice to Applicant's rights to file a divisional application thereto.

Claims 1-45 have been selectively amended in order to clarify claimed structure which is deemed to patentably distinguish over the applied art. This will become evident from the further detailed consideration.

Claims 54-57 have been added as dependent from pending claims and are drawn

to the elected invention.

Basically, the invention is directed to a fracture fixation system which comprises a wire element 10 which serves to engage and position an unstable bone fragment 4 on one side of a fracture and a washer 12 which secures the wire element to a stable bone fragment 5 on the other side of the fracture by a bone screw 11.

Medoff '682 shows a buttress element and washer of similar type but lacks (1) critical features relating to the length and spacing of the legs of the wire element and (2) means for preventing the washer from rotating when the bone screw is screwed into the stable bone. It will be demonstrated hereafter that these critical features are not disclosed in Medoff '682 nor are they remotely suggested by the Wellisz '884 patent.

Rejection of Claims 1, 4-5, 6-7, 12, 13, 22-23, 26-28 and 38-41

The above claims have been rejected under 35 U.S.C. 102 as being anticipated by Medoff '682. These claims include the construction of the washer 12 as illustrated in Figs. 4, 9 and 10-16.

The claimed washer is clearly distinguished from Medoff '682 in that the washer is provided with a means for applying a counter-bearing pressure on one of the legs of the wire element to oppose rotation of the washer when the bone screw is screwed into the stable bone fragment. Medoff '682 shows no such structure or any means for preventing rotation of the washer when the bone screw is being installed.

Referring, for example, to Medoff '682 therein are seen washers having end tabs (see Figs 4 and 9-11) for engaging opposite legs of the wire element. Clearly, absent in these drawings is any means for applying a counter-bearing pressure on one of the legs of the wire element to prevent the washer from rotating when the bone screw is screwed into the bone (see the specification of the present application in paragraph [00064] at line 6 where it is also stated that this prevents slippage of the washer from the legs). Hence, in order to prevent slippage of

the washer 12 from the legs of the buttress pin and spinning of the washer as the bone screw 11 is screwed into the bone fragment (as could be the case in Medoff '682), a further tab 44 is bent out of the plane of the body 40 of the washer to face the pair of tabs 42 and define a clear space 45 therebetween in which the leg 15 is received.

The tabs 42 bear against the outer surface of leg 15 while the tab 44 bears against the inner surface of leg 15 to apply a counter-pressure on leg 15 as the bone screw is turned and thereby to prevent the relative rotation of the washer with respect to the wire element and slippage of the washer off the legs of the wire element. Medoff '682 discloses no means whatsoever to prevent such rotation of the washer or slippage thereof from the legs of the wire element when the screw is inserted through the hole in the washer into the bone.

In rejecting Claim 1, the Examiner attributes the means for providing counter-bearing pressure on one of the legs of the wire element as the combination of the washer tabs (ends of 46 and the bone screw 44). In the first place, no counter-bearing pressure is shown against one of the legs of the wire element and secondly Medoff '682 shows no recognition of the problems of slippage of the washer off the wire element nor any means by which this could be accomplished. It is respectfully submitted that the ends of washer 46 and the bone screw do not qualify as the means for preventing rotation of the bone screw as it is inserted into the bone. The bone screw itself is responsible for the development of the force which will spin the washer as the bone screw is inserted into the bone and thus cannot contribute as a means to prevent rotation of the washer. The ends of the washer 46 are equivalent to the plurality of tabs which engage the legs of the wire element. The means as recited in Claim 1 apply a counter-bearing pressure on one of the legs of the wire element to oppose the rotation of the washer when the bone screw is turned for engagement in the stable bone. This function is achieved by the tab 45 or 64 or 75 which acts in opposition to the tabs normally engaging the same leg of the wire element to apply the counter-bearing pressure on the leg of the wire element.

Nevertheless, Claim 1 has been amended to be more specific to the provision of the tab which opposes the conventional tabs on the wire element, to develop the counter bearing pressure to oppose the rotation of the washer with respect to the wire element. No such tab is

shown in Medoff '682 and this patent neither discusses the problem of spinning of the washer or provides any structure which could solve the problem. It is clear that Medoff '682 does not show a counter opposing tab.

With respect to Claim 4 this is directed to the projection 26 having a hole 27 longitudinally spaced from the hole 43 (for the bone screw 11) to receive a fastener, such as second bone screw 28 which not only secures the wire element to the unstable bone fragment 4 (as distinguished from bone screw 11 which secures the washer to the stable bone fragment 5) but it also acts to buttress the articular unstable bone fragment (see Fig. 2). In Medoff '682 the second leg 16 in Fig. 9 (as cited by the Examiner) is provided for receiving a second bone screw adapted to secure the wire element to the bone fragment. In the first place, the second bone screw is not placed in a projection which extends longitudinally from the washer so that the second bone screw can be secured to the unstable bone fragment and the second bone screw in Medoff '682 (Fig. 9) secures the wire element to the same bone fragment as the first bone screw.

With regard to Claim 5, herein it is stated that the fixation element 28 and the bent portions at the distal ends of the legs of the wire element extend at an angle to one another as shown in Fig. 2. Medoff '682 does not show such fixation element nor any angular relationship between the bent ends of the wire element and the fixation element. With respect to the Examiner's comments concerning the Abstract for disclosing the securing of a second bone fragment, this is not achieved by the means which has been claimed but refers in general to the clamping arrangement of the fixation device itself.

With regard to Claim 6 herein it is recited that the legs of the wire element are spaced from one another and have a reduced spacing at the U-shaped bend as compared to the spacing of the legs at the distal ends thereof. This is illustrated for example, in Figs. 3 and 5 and elsewhere and it is not seen that the Examiner has addressed this feature in the rejection of Claim 6.

Claim 7 adds the feature that the legs are of equal length.

In a subsequent comment addressed to the features of Claims 6 and 7, the

Examiner considers that the features that the legs are of unequal shape would have been an obvious matter of design choice to one skilled in the art “since Applicant has not disclosed that such [features] solve any stated problem or is anything more than one of numerous shapes or configurations the person [of] ordinary skill in the art would find obvious....” Applicant strongly contends that the shape of the wire element is not a trivial or unobvious matter since the offset length and width are capable of transferring loads across an oblique articular surface to a linear support structure (base of the wire element) along the bone shaft. In addition, since these devices are frequently curved out of the plane of the base of the wire as well, the wire elements cannot be simply angled to one side or the other to adapt to an oblique surface. Offset width solves the problem of addressing a bone that is wide at the distal end and narrows proximally by providing support across the wide articular surface with a base of fixation and particularly allows two implants to be placed side by side along a narrow shaft (see Figs. 7-9). As this is dependent on the site of application, these shapes provide additional complexity to the configuration of the implant and are not a simple matter of choice selectable from existing art. Contrary to the argument of the Examiner that application has not disclosed that the shapes of the wire elements solve any stated problem and would be obvious, the shapes of the legs of the wire element and the problems that they solve are set forth in paragraph [0009], paragraphs [00056], [00057] and [00058] by way of example.

With regard to Claim 13 this claim is directed to the fixation washer per se and is specifically addressed to the further tab positioned for engaging the wire form in counter-bearing opposition to the opposed plurality of tabs on opposite sides of the wire form to prevent rotation of the washer as the bone screw is screwed into the bone. This claim finds no response whatever in Medoff ‘682 which fails to show any tabs other than the ones that engage the top of the wire element. Claim 13 has been amended similarly to Claim 1 to clearly establish that the additional tab is opposite the plurality of tabs in counter bearing opposition on the same leg.

Claims 22, 23 and 26 are dependent from Claim 13 and further define features of the washer. Claim 26 is significant as it is addressed to the projection 26 on the washer body to receive the additional bone screw as shown in Fig. 8. No such construction or function is evident in Medoff ‘682.

With regard to Claim 27, this is drawn to the fracture fixation system including the buttress member and the washer and herein is recited the provision of the second hole adapted for insertion of a fixation element for being secured to the unstable bone fragment. As previously noted, this is directed to the projection 26 and its utilization for securing the second bone screw 28. The second bone screw of Medoff '682 is adjacent to the first bone screw and both bone screws are secured to the same stable bone. Amended Claim 27 clearly distinguishes over Medoff '682 as it is now recited that the second hole is longitudinally spaced from the first bone screw hole. Furthermore, the second hole is in a position so that a fixation element (bone screw) will be secured to the unstable bone fragment.

With respect to Claims 38-41 these claims are specifically addressed to a volar buttress pin and recite the reduced spacing of the end of the wire element adjacent to the U-shaped bend as compared to the spacing in proximity to the distal ends (which provide the buttressing function). This has been previously discussed and it is respectfully submitted that Medoff '682 cannot meet the terms of the claim and the spacing is not an obvious modification as alleged by the Examiner.

The Examiner has indicated the allowability of Claims 11 and 45 which are addressed to a particular means by which the different spacing at the ends of the wire element can be obtained.

Claims 2-3, 14-21, 30-34 and 35-37

These claims are rejected as being unpatentable over Medoff '682 in view of Wellisz '884.

Medoff has been cited for disclosing subject matter previously discussed and the Examiner acknowledges that Medoff lacks "a further tab on the washer to engage one opposite side of a leg, capable of snap engagement, a means for applying counter bearing pressure to oppose rotation, is inclined where one tab is disposed between two tabs, and wherein the second hole is capable of offsetting the buttress portions".

The acknowledgement that Medoff lacks these features would appear to disqualify Medoff as a 102 reference against the claims drawn to the washer or the washer in combination with the wire element which include the further tab and the means for applying counter bearing pressure to oppose rotation of the washer. It would also seem to disqualify Medoff as a 102 reference where the claims include the second hole capable of offsetting the buttressing portions.

Wellisz '884 discloses a clip 310 for securing two elements together, namely a skull segment 11 to the cranium 13 following brain surgery. The clip 310 has one end portion for being secured into the skull segment 11 and an opposite end for being secured to the cranium at an edge thereof. In the first place it is not seen how Wellisz '884 could be remotely associated with Medoff '682 as these are directed to entirely different structures for achieving different purposes. Furthermore, the clip in Wellisz '884 is totally dissimilar in construction and function from the fixation device of Medoff.

In Wellisz '884 the clip 310 has means for securing the clip to the edge of the cranium at the opening where the skull segment 11 has been removed. A gap 16 is formed between the facing edges of the skull segment and the cranium and the clip of Wellisz '884 is intended to engage in the gap 16 and secure the skull segment to the cranium. The clip of Wellisz '884 includes a flap 320 which sits on the upper surface of the cranium beyond the gap 16 and a flexible projection or tab 322 is carried by flap 320 to extend into the gap 16. The flexible projection 322 has an end 322b which is sharpened to gouge into the edge surface of the cranium. In this regard, the projection is made flexible by bend 380 and it has a width which exceeds that of the gap 16 so that when the projection is pushed into the gap it will flex and exert pressure on the sharpened end 322b so that it will gouge into the edge of the cranium. It is seen that the edge 322b gouges into the side surface of the cranium while the bend 380 bears against the edge of the skull segment. This produces fixation of the projection to the end edge of the cranium and a biasing force against the skull segment.

It is respectfully submitted that one skilled in the art would not have any motivation or suggestion of how to employ the clip of Wellisz '884 to Medoff '682 to provide an additional tab on the washer which would engage the wire element on an opposite side thereof to

provide counter-bearing pressure so that when the mounting screw is being secured in the bone the washer would be prevented from rotating. The clip of Wellisz '884 is neither constructed for nor can it function to secure the wire element of Medoff '682 to the underlying bone. It is thus respectfully submitted that Wellisz '884 would not be suitable under 35 U.S.C. 103 for addition to Medoff '682 which uses the wire element for fixation of the unstable and stable bone segments and the washer for securing the wire element to the stable bone. The Examiner states that it would be obvious to employ the clip of Wellisz '884 with a rod to secure the plate in use. The Examiner refers to "column 61-67 ? through column 5, line 37". Working backwards from column 5, line 37, through column 4, there is not seen any remote suggestion that the clip of Wellisz '884 is capable of engagement with a rod. Indeed, this would be so disparate from the connection of the skull segment 11 to the cranium 13 as not to have any possible teaching relevant to the use of a wire element.

As to secondary features, the Examiner's contention that Wellisz '884 shows a snap engagement is without foundation as a snap engagement requires an elastic deformation of one element followed by a resilient return. This occurs when the second tab of the washer is elastically deformed and then snaps over the wire element as illustrated in Fig. 12 by way of example. The pressure on the sharp end of the projection 322 in Wellisz '884 does not provide a snap engagement. The sharp end of the projection 322 gouges the edge of the cranium under resilient force of the bend and becomes fixed in the sidewall of the cranium.

The rejection of Claims 8-10, and 42-44 over Medoff '682 is inapplicable for the reasons which have been previously discussed and are not repeated herein.

New Claims 54-57

Claim 54 is dependent from Claim 2 and specifies that the further tab and the opposing tab are positioned for engaging a round cross-section of the wire element on opposite sides thereof. This is clearly illustrated in Figs. 12-16. The specification has been amended to provide specific antecedent support for the round cross-section of the wire element. This explicit limitation in Claim 54 clearly demonstrates the absence of anything similar in Medoff '682.

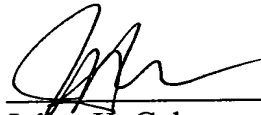
Claim 55 is dependent on Claim 13 and is similar to Claim 54.

Claims 56 and 57 are directed to the configuration shown in Fig. 9 where two buttress members are placed adjacent to one another and the washer engages one leg of each of the two buttress members.

Conclusion

In view of the above action and comments, it is respectfully submitted that the claims in the application are now all in allowable condition and favorable reconsideration is earnestly solicited.

Respectfully submitted,



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